IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NEXUS PHARMACEUTICALS, INC., Plaintiff, v. EXELA PHARMA SCIENCES, LLC, Defendant.	C.A. No. 22-1233-GBW

DEFENDANT'S OPENING BRIEF IN SUPPORT OF ITS MOTION FOR JUDGMENT AS A MATTER OF LAW

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I. INTRODUCTION

Ephedrine sulfate is a 100-year-old drug that has been used in anesthesia to treat hypotension for decades. Tr. 780:12-14, 779:10-14 (Powell). And it has been administered to patients in a 5 mg/mL concentration, with 9 mg/mL saline, from a syringe for that entire period. Tr. 782:6-11, 784:2-10, 792:8-12 (Powell). Sometimes this 5 mg/mL formulation was prepared at bedside by physicians; sometimes it was pre-prepared in hospital pharmacies; sometimes it was purchased from 503B compounding facilities. Tr. 784:2-10, 786:8-16, 788:18-20 (Powell). But in every instance, it was the same drug, in the same concentration and formulation, used for the same purpose. Yet, somehow, Nexus Pharmaceuticals Inc. (Nexus) received patents on this old product, including the three Asserted Patents.[1] And wielding those patents, Nexus has subjected Exela Pharma Sciences, LLC (Exela) to years of baseless litigation over Exela's AKOVAZ PFS product.

The jury saw Nexus for what it was—a company trying to get a windfall payday to the detriment of patient costs—and found Exela not liable for any of the over $89 million in damages Nexus demanded. But, in what appears to be a compromise verdict, the jury reached unsupported conclusions as to the infringement and validity of certain claims. As explained below, the jury's verdict on those claims is unsupported under the law and the Court should enter judgment as a matter of law in favor of Exela.

II. NATURE AND STAGE OF THE PROCEEDINGS

The Court held a five-day jury trial on August 25-29, 2025. Following trial, the Court found no pre-suit willfulness on JMOL (Tr. at 1122:12-19; D.I. 358 at 2), and the jury returned a verdict for Exela. D.I. 342. It found that Exela does not infringe any valid claim and that Nexus

[1] U.S. Patent Nos. 11,426,369, 11,464,752, and 11,571,398.

is entitled to no damages. Specifically, the jury found that Exela does not infringe claims 6 and 9 of the '369 patent and claim 1 of the '398 patent. And it found claim 7 of the '752 patent obvious. As to the noninfringed claims, the jury found that Exela had not proven they were obvious. As to invalid claim 7, the jury found post-suit willful infringement.

The Court entered judgment on the jury's verdict on September 18, 2025 (D.I. 358) and set a briefing schedule for the filing of post-trial motions (D.I. 359). Exela now moves for judgment as a matter of law of no infringement of claim 7 of the '752 patent, no willful infringement, and obviousness of '369 patent claims 6 and 9 and claim 1 of the '398 patent.

III. SUMMARY OF ARGUMENT

Non-infringement of '752 Patent Claim 7: This claim requires that the ephedrine sulfate composition be terminally sterilized for "about 15 minutes." Exela's AKOVAZ PFS product is not; there is no dispute that AKOVAZ PFS is terminally sterilized for "not less than 30 minutes"—*i.e.* ***30 minutes or more***. PTX-86 at 13; Tr. 396:5-11 (Fix). No reasonable jury could conclude that "about 15 minutes" is met by terminal sterilization for ***double*** (or more) the required time. Nexus's only purported evidence on this point is its expert's testimony that "you can't get to 30 minutes of time unless you've been to 15 minutes already" (Tr. 396:12-19 (Fix)), which improperly ignores the actual claim limitation and treats the claim as if it instead says "at least 15 minutes." It does not. Nexus thus lacks any evidence of infringement of this limitation of claim 7, rending this claim not infringed as a matter of law.

No Willful Infringement: Because there is no infringement of claim 7 of the '752 patent as a matter of law, there can be no willful infringement. But even beyond that, Nexus failed to present sufficient evidence for a reasonable jury to find post-suit willful infringement. The sum total of evidence Nexus presented on willfulness was Nexus's pre-suit letters that informed Exela of the existence of a patent ***not*** in suit and ***applications*** that led to the patents-in-suit, followed by

Nexus's filing of multiple complaints against Exela immediately after each patent-in-suit issued. At best, this evidence shows that Exela became aware of each patent as Nexus filed its lawsuits. But willfulness requires more than mere knowledge of the patent. On this record no reasonable jury could find post-suit willfulness.

Invalidity of '369 Patent Claims 6 and 9 and '398 Patent Claim 1: The record lacks substantial evidence to support a jury finding that the asserted claims of the '369 and '398 patents are not invalid as obvious. The jury determined that claim 7 of the '752 patent is invalid as obvious, and claim 7 recites the exact same 5 mg/mL ephedrine sulfate formulation as the asserted claims of the '369 and '398 patents. For most of the limitations in the claims, there was no dispute that they were taught by the prior art, particularly the prior art AKOVAZ concentrate product and the Akers textbook. Nexus admitted that the prior art teaches the formulation, had no substantive response to the explicit teaching of the claimed steps in the Akers textbook, and did not dispute that the prior art teaches the administration and testing condition limitations.

Nexus's only substantive dispute was on the claimed stability limitations—a pH within 0.5 units of the starting pH, an ephedrine sulfate concentration of 95% of the packaged concentration, a bacterial endotoxin level of less than 7 EU/mg, and an individual impurity level of not more than 0.2%—but the evidence overwhelmingly demonstrates that the prior art ephedrine sulfate is highly stable as to all the claimed conditions in glass containers. In fact, the AKOVAZ concentrate product that was sold in glass vials (an embodiment undisputedly covered by the claims) before the date Nexus filed its patents met ***all the claimed stability parameters*** at the ***claimed conditions***, for the ***claimed lengths of time*** (6 and 12 months)—indeed, the AKOVAZ concentrate product retained these claimed stability characteristics for ***four years***.

With all the limitations taught in the art, motivation to combine and reasonable

expectation of success can't save Nexus's claims. Because the jury found claim 7 of the '752 patent to be obvious, the jury necessarily found a motivation to combine the prior art references, and found that there would have been a reasonable expectation of success in achieving the two limitations recited in claim 7, including the same concentration limitation (95% of the packaged concentration of ephedrine sulfate after storage at the claimed conditions for the claimed time). There is no reason (or evidence to support) why any of the other claimed stability limitations should be any different. The claimed endotoxin and impurity levels, like the concentration levels, are simply FDA's regulatory requirements that necessarily had to be met by the prior art AKOVAZ concentrate. As to pH, Nexus's only purported evidence that a POSA would have expected the pH to drift by more than 0.5 units is a single, self-serving statement in a later-filed (i.e. non prior art) patent to another company (Nevakar) about supposed pH drift. But as shown at trial, Nexus previously argued to a different court that Nevakar's pH drift statement is ***false***. Setting aside the impropriety of Nexus's counsel having its expert rely on information Nexus itself believes to be false, the pH drift statement is legally insufficient to support a finding of nonobviousness. Thus, there is no substantial evidence to support a verdict of nonobviousness of the asserted claims of the '369 and '398 patents.

IV. LEGAL STANDARD

A court should grant judgment as a matter of law if it finds that "a reasonable jury would not have a legally sufficient evidentiary basis to find for [a] party" on an issue. Fed. R. Civ. P. 50(a)(1). "[W]here the movant bore the burden of proof on an issue, JMOL is only granted where 'there is insufficient evidence for permitting any different finding.'" *Amgen Inc. v. Hospira, Inc.*, 944 F.3d 1327, 1333 (Fed. Cir. 2019) (quoting *Fireman's Fund Ins. Co. v. Videfreeze Corp.*, 540 F.2d 1171, 1177 (3d Cir. 1976)). On issues for which the moving party did not bear the burden of proof at trial, a party is entitled to judgment as a matter of law "if,

viewing the evidence in the light most favorable to the nonmovant and giving it the advantage of every fair and reasonable inference, there is insufficient evidence from which a jury reasonably could find liability." *Biogen MA Inc. v. EMD Serono, Inc.*, 976 F.3d 1326, 1331 (Fed. Cir. 2020) (quoting *Lightning Lube, Inc. v. Witco Corp.*, 4 F.3d 1153, 1166 (3d Cir. 1993)).

V. ARGUMENT

A. '752 Patent, Claim 7: Exela Does Not Terminally Sterilize for "About 15 Minutes"

No reasonable jury could have found that AKOVAZ PFS infringes claim 7 of the '752 patent because Nexus presented no evidence to support a finding that the product is terminally sterilized for "about 15 minutes," as required by the claim. The reason for Nexus's failure of proof? Exela's manufacturing process unambiguously—and undisputedly—requires that AKOVAZ PFS be terminally sterilized for not less than 30 minutes. PTX-86 at 13; Tr. 396:5-11 (Nexus's Dr. Fix explaining that Exela terminally sterilizes for "not less than 30 minutes"); Tr. 946:23-947:14 (Exela's Dr. Myers explaining the same); *see also* Tr. 732:18-19 (Exela's Kelly Abernethy testifying that Exela terminally sterilized for 30 minutes). "Not less than 30 minutes" is not "about 15 minutes" under any reasonable interpretation, and no reasonable jury could conclude otherwise.

When a party fails to prove an element of the *prima face* case for a burden-bearing issue, judgment as a matter of law must be entered against it. *See TI Grp. Auto. Sys. (N. Am.), Inc. v. VDO N. Am., LLC*, 375 F.3d 1126, 1133 (Fed. Cir. 2004) ("[JMOL] is appropriate where 'the record is critically deficient of the minimum quantum of evidence' in support of the verdict." (quoting *Gomez v. Allegheny Health Servs., Inc.*, 71 F.3d 1079, 1083 (3d Cir. 1995))). Here, Nexus did not submit any evidence demonstrating that AKOVAZ PFS is terminally sterilized for "about 15 minutes." In fact, Exela's product is held at high heat for at least twice as long.

At trial, Nexus did not even attempt to prove that Exela terminally sterilizes for "about 15 minutes." Dr. Fix (Nexus's technical expert) did not testify, for example, that "not less than 30 minutes" is literally or equivalently within the scope of "about" in the claimed "about 15 minutes." Nor could he have credibly done so. It is self-evident that 30 minutes is twice as long as 15 minutes. Faced with that factual reality, Dr. Fix testified as follows:

> Q. Well, as you just pointed out, Doctor, they terminally sterilize for not less than 30 minutes. The claim says about 15 minutes. How does that change your analysis?
>
> A. It doesn't change my analysis. They still practice according to the claim because, put it simply, ***you can't get to 30 minutes of time unless you've been to 15 minutes already***. So they meet that claim limitation.

Tr. 396:12-19 (emphasis added). This single Q&A represents the entire universe of evidence Nexus offered on this issue. Dr. Fix, and Nexus, ignored the actual claim limitation entirely.

In essence, Nexus and Dr. Fix rewrote the claim from requiring terminal sterilization for the specified amount of time ("about 15 minutes") to requiring terminal sterilization for "at least" a lower limit of 15 minutes. Such an interpretation is inconsistent with any plain meaning understanding of "about 15 minutes," as is readily apparent from even a cursory application of basic claim construction principles. Considering first the context of the claims themselves, claim 7 depends from claims 5 and 6 of the '752 patent. JTX-5.27. Claim 5 covers a product: an ephedrine sulfate syringe. *Id.* Among other things, that product must contain "***at least*** 95% of the packaged concentration" of ephedrine sulfate." *Id.* Claim 5 thus confirms that the patentee knew how to draft a claim to cover anything more than "at least" a minimum amount, and suggests the patentee's choice not to use that language in claim 7 was intentional.

Claim 6—depending from claim 5— then adds details about the process of making the claimed product: the ephedrine sulfate must be terminally sterilized in the syringe. *Id.* Said differently, claim 6 claims the broader concept of terminally sterilizing in general. And claim

7—the only claim from the '752 patent that Nexus brought to trial—adds specific requirements for the terminal sterilization process: the syringes must be heated "at about 122° C. for about 15 minutes." *Id.* As shown by the claim structure itself, claim 7 is an intentionally narrow claim directed to a specific terminal sterilization process, one that precisely tracks the narrow disclosure in the specification. JTX-5.13 at 17:31-33 ("The capped vials were crimped and ***sterilized by the overkill approach at 122.1° C. for 15 minutes*** in steel cassettes in an A601A autoclave."). Altogether, the claims themselves show that what Nexus attempted to do at trial—rewrite the claims such that they cover "about 15 minutes" ***plus anything longer***—is legally unsound and not something a reasonable juror could accept.

Because Dr. Fix's testimony goes to a limitation not present in claim 7 (i.e., terminal sterilization for "***at least*** about 15 minutes"), and because the undisputed record establishes that Exela does not terminally sterilize for the claimed period (i.e., "about 15 minutes"), the Court should enter JMOL of no infringement. *See TI Grp.*, 375 F.3d at 1133.

That said, even accepting Nexus's and Dr. Fix's erroneous interpretation, Nexus failed to prove infringement for a second reason. Nexus did not prove that Exela's AKOVAZ PFS is a "sterilized ephedrine composition" at "about 15 minutes." JTX-5.27. As discussed, claim 7 is a product claim, not a process claim. So, to prove infringement under Nexus's interpretation, Nexus was required to prove that all the limitations of claim 7 are found in the AKOVAZ PFS product at the claimed "about 15 minutes" mark during the AKOVAZ PFS terminal sterilization process. Said another way, Nexus was required to prove that AKOVAZ PFS infringes claim 7—each one of its limitations—midway through the AKOVAZ PFS terminal sterilization cycle.

Claim 7 independently requires that the product be a "sterilized ephedrine composition." JTX-5.27. There is no evidence about any characteristic of AKOVAZ PFS when the product is

about 15 minutes into its not less than 30-minute terminal sterilization cycle. There is certainly no evidence that AKOVAZ PFS is, in fact, sterile half-way through that cycle. The record strongly suggests it is not. As Exela's Director of Execution, Ms. Kelly Abernethy, explained, anything short of the full 30-minute cycle fails to meet sterility assurance and must undergo another cycle. Tr. 741:4-24. Nexus therefore failed to prove claim 7's "sterilized ephedrine sulfate" limitation when it contended that having "been to 15 minutes already" was adequate to meet the "about 15 minutes" limitation. This independently supports JMOL of noninfringement.

B. There Is Legally Insufficient Evidence for a Reasonable Jury to Find Exela Willfully Infringes Claim 7 of the '752 Patent

As explained above, Exela does not infringe claim 7 of the '752 patent. Since there must first be infringement for there to be willful infringement, the Court should enter JMOL that Exela does not willfully infringe claim 7. *See Innovative Pats., L.L.C. v. Brain-Pad, Inc.*, 719 F. Supp. 2d 379, 387 (D. Del. 2010) ("Inasmuch as there is no infringement of [a patent], the issue of willful infringement of that patent 'necessarily drops out of the case.'" (quoting *Read Corp. v. Portec, Inc.*, 970 F.2d 816, 830 (Fed. Cir. 1992))).

Even assuming the jury's finding of infringement stands, no reasonable jury could have found that Exela willfully infringes claim 7 of the '752 patent. The Court already granted JMOL of no pre-suit willfulness (Tr. at 1122:12-19; D.I. 358 at 2), and Nexus introduced no legally sufficient evidence to show post-suit willful infringement either. At trial, Nexus presented two general categories of evidence: (1) a sequence of pre-suit, pre-issuance letters to Exela and Exela's counsel notifying Exela of certain patents and applications; and (2) the various complaints in this action, including amended complaints. Because Federal Circuit precedent and case law in this District establish that both categories of evidence are insufficient as a matter of law to support a finding of willfulness, the jury's verdict cannot be sustained.

The pre-suit, pre-issuance letters cannot support a finding of willfulness post-suit for the same reasons they cannot support a finding of willfulness pre-suit. First, the letters identify only one issued patent, U.S. Patent No. 11,090,278—a patent not asserted in this case. *See* PTX-1587; Tr. at 235:3-25 (Ahmed). The letters also refer to the then-pending Patent ***Application*** Nos. 17/381,770 and 17/556,904—later issued as the '752 and '369 patents. *See* PTX-1587; PTX-1588; PTX-1589; DTX-1091; Tr. at 235:3-25 (Ahmed); *Id.* at 688:7-14 (Koneru). This is legally insufficient because "[t]o willfully infringe a patent, the patent must [1] ***exist*** and [2] one must have ***knowledge*** of it." *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1236 (Fed. Cir. 1985) (emphasis added).

As a matter of law, mere knowledge of a patent application is insufficient to support a finding of willfulness. *State Indus.*, 751 F.2d at 1236 ("Filing an application is no guarantee any patent will issue and a very substantial percentage of applications never result in patents."); *see also Verint Sys. Inc. v. Red Box Recorders Ltd.*, No. 14-5403, 2016 WL 7177844, at *2-3 (S.D.N.Y. Dec. 7, 2016) (no willfulness because knowledge of application is insufficient to show knowledge of issued patent). Further, mere knowledge of an issued patent—absent other evidence—is insufficient for a finding of willfulness. *Bayer Healthcare LLC v. Baxalta Inc.*, 989 F.3d 964, 988 (Fed. Cir. 2021); *Cloud Farm Assocs., L.P. v. Volkswagen Grp. of Am., Inc.*, No. CA 10-0502-LPS, 2012 WL 3069390, at *2 n.2 (D. Del. July 27, 2012).

Likewise, Nexus's complaints, filed starting less than a month after the first patent issued, "cannot serve as the basis for a defendant's actionable knowledge for a willful infringement claim." *See Cleveland Medical Devices, Inc. v. ResMed, Inc.*, 696 F. Supp. 3d 4, 13-14 (D. Del. 2023); *see also Pact XPP Schweiz AG v. Intel Corp.*, No. 19-1006-JDW, 2023 WL 2631503, at *5 (D. Del. Mar. 24, 2023) ("There are many reasons why a complaint can't constitute the basis

[for] willful infringement, among them that a complaint can't constitute an element of a claim that it purports to raise, and that it would mean all infringement suits involve willful infringement."). That a complaint alone is insufficient for post-suit willfulness makes sense because all it shows is knowledge, which "is necessary, ***but not sufficient***, for a finding of willfulness." *Bayer Healthcare LLC*, 989 F.3d at 988.

As the Court previously summarized (Tr. at 1122:20-1123:5), the letters and complaints are the totality of Nexus's willfulness evidence. What remains supports only a ***lack*** of willfulness, with Exela vigorously contesting both the infringement and validity of the three asserted Nexus patents from day one of the suit. D.I. 20. Those good faith, reasonable defenses defeat any post-suit willfulness claim. *See e.g.*, *Gustafson, Inc. v. Intersystems Indus. Prods., Inc.*, 897 F.2d 508, 511 (Fed. Cir. 1990) ("[A] party may continue to manufacture and may present what in good faith it believes to be a legitimate defense without risk of being found on that basis alone a willful infringer."); *Wrinkl, Inc. v. Facebook, Inc.*, No. 20-1345-RGA, 2021 WL 4477022, at *8 (D. Del. Sept. 30, 2021) ("[I]f all that is required is the filing of a complaint and a plausible allegation of infringement" to give rise to post-suit willfulness, "then every case would be a willful infringement case."); *Plastic Omnium Advanced Innovation & Rsch. v. Donghee Am., Inc.*, 387 F. Supp. 3d 404, 422 (D. Del. 2018), *aff'd*, 943 F.3d 929 (Fed. Cir. 2019) (granting summary judgment of no post-suit willful infringement where plaintiff did not seek preliminary injunction and defendant asserted reasonable defenses). Nexus never sought a preliminary injunction, and Exela maintained reasonable and good faith defenses throughout the case—and the jury agreed, finding no liability. Given the good faith and reasonableness (and success) of Exela's defenses, Exela's conduct during this litigation cannot be considered willful. *See State Indus.*, 751 F.2d at 1236-37 (finding defendant's actions during suit did not give rise to

willfulness given nonfrivolous defenses as to validity and infringement).

In sum, evidence of knowledge of a pending application is insufficient as a matter of law to support a finding of willfulness of the latter issued patent. *Id.* at 1236, 1238. And evidence of knowledge of the patents combined with good faith defenses against infringement and validity is even more insufficient. *Id.* at 1237-38. The Court should therefore grant judgment as a matter of law of no willful infringement for claim 7 of the '752 patent.

C. There Is Insufficient Evidence for a Reasonable Jury to Find Claims 6 and 9 of the '369 Patent and Claim 1 of the '398 Patent Not Obvious

No reasonable jury could have found that the claims of the '369 and '398 patent are not invalid as obvious over the combination of the AKOVAZ concentrate product and the Akers textbook teaching POSAs the known steps for making sterile drug products. The jury already determined that claim 7 of the '752 patent is obvious, which the evidence supports, so it necessarily found that a POSA would have had a reason to combine AKOVAZ concentrate with Akers. And the existence of the compounded CAPS and IntegraDose products demonstrates that a POSA was motivated to make 5 mg/mL pre-filled syringes of ephedrine sulfate.

1. There is no dispute that the claimed formulation, method steps, administration steps, and testing conditions were well known to POSAs prior to May 16, 2019

No reasonable jury could have found that claims 6 and 9 of the '369 patent and claim 1 of the '398 patent were not obvious because the evidence presented at trial proved beyond dispute that all the claim elements were well-known to the POSA prior to the effective filing date of May 16, 2019, and that a POSA would have been motivated to combine those prior art elements with a reasonable expectation of success.

Formulation: The formulation recited in the asserted claims (5 mg/mL ephedrine sulfate, 9 mg/mL sodium chloride and water, with no preservative) was taught by the 2016 label for the

AKOVAZ concentrate product (DTX-236.2), and had been prepared by hospitals and compounding pharmacies and used by physicians for more than a decade (Tr. 779:10-14, 780:12-14, 786:8-16 (Powell)). None of this is disputed. Nexus's own expert, Dr. Fix, admitted that the claimed formulation had been known and used for decades. Tr. 1035:7-1036:8 (Fix); *see also* Tr. 830:3-11 (Nexus's Regulatory Affairs Lead, Jagdeep Kaur, testifying that the AKOVAZ label taught the preparation of the same 5 mg/mL ephedrine sulfate solution that Nexus proposed to the FDA). And Nexus knew the prior art CAPS compounded syringes used the claimed formulation, having admitted as much in prior litigation seeking to remove those compounded products from the market. Tr. 215:22-216:22 (Ahmed); DTX-265.22-23; *see also* DTX-25.19, DTX-26.11. In addition to Nexus's witnesses, Exela's expert Dr. Myers also testified that the claimed formulation was well known to POSAs because it was instructed by the AKOVAZ label and prepared well before May 2019 by compounding pharmacies, including CAPS and IntegraDose, as well as in his own work as a compounder. Tr. 867:12-20; 877:16-878:25 (Myers); *see also* Tr. 861:24-862:20 (Myers); DTX-330.2.

Moreover, the jury necessarily found the claimed formulation (5 mg/mL ephedrine sulfate, 9 mg/mL sodium chloride and water, with no preservative) to be obvious because it is the same formulation claimed by the '752 patent, which the jury invalidated as obvious over the prior art, a finding supported by the evidence discussed above. *Polara Eng'g Inc v. Campbell Co.*, 894 F.3d 1339, 1351 (Fed. Cir. 2018) ("Following a jury verdict on obviousness, 'we first presume that the jury resolved the underlying factual disputes in favor of the verdict and leave those presumed findings undisturbed if they are supported by substantial evidence.'" (quoting *Kinetic Concepts, Inc. v. Smith & Nephew, Inc.*, 688 F.3d 1342, 1356-57 (Fed. Cir. 2012))).

Manufacturing steps: The manufacturing method steps of claims 6 and 9 of the '369 patent (including those recited in claim 1, from which claims 6 and 9 depend) are also obvious in light of the prior art, and no reasonable jury could have found otherwise. The claims simply recite the basic manufacturing steps fundamental for any sterile injectable product—combining the ingredients into a batch solution, filtering that batch solution, sanitizing containers and then filling those containers with the filtered solution, sealing the filled containers, and then sterilizing the sealed containers. JTX-1.27; DTX-240.193, .195. As Dr. Myers explained at trial, these basic steps are "right out of the Akers textbook"—a textbook published in 2010 that describes methods for formulating and manufacturing sterile drug products like the products at issue here. Tr. 876:16-21, 912:8-16, 913:20-23, 922:17-24 (Myers).

Nexus did not dispute that the prior art taught each of the '369 patent method steps. Nor could it since Nexus's Senior Director of Research and Development admitted at deposition that she was personally aware of each of the claimed method steps being used to make other drug products prior to 2019. Tr. 814:4-24 (Tawde). Instead, Nexus's only argument in response to the Akers disclosures was that Akers could not invalidate the '369 patent because it is "huge," contained "tons of information." Tr. 1018:4-23 (Fix). A reference being large is not a defense to obviousness. The hypothetical POSA "is presumed to be aware of all the pertinent prior art," *Standard Oil Co. v. Am. Cyanamid Co.*, 774 F.2d 448, 454 (Fed. Cir. 1985), and there is no dispute that the knowledge conveyed in Akers is within that realm. Nexus's argument is particularly baseless here, where Akers shows claimed manufacturing steps are together in a simple flowchart, in addition to describing them together in a single paragraph. Tr. 923:3-925:6 (Myers); DTX-240.193 (flowchart disclosing each method step of claims 1 and 9 of the '369 patent); DTX-240.195 (describing each method step required by the same claims).

Storage conditions: The claimed storage conditions—25°C and 60% relative humidity for at least 12 months or 40°C and 75% relative humidity for at least 6 months—were also well-known to the POSA prior to May 2019, a fact that Nexus does not dispute and that the jury necessarily agreed with in rendering its obviousness verdict as to claim 7 of the '752 patent, which contains these exact conditions. The claimed storage conditions are standard testing conditions published in the ICH Guidelines and required by FDA for stability testing of injectable drug products stored in glass containers. Tr. 896:18-897:12 (Myers); DTX-88.9. As Akers explains, these stability conditions are the "Basic Requirements of ICH Stability Guidelines." DTX-240.374. Indeed, Nexus's Regulatory Affairs Lead, Jagdeep Kaur, testified that the claimed conditions were derived from the ICH Guidelines. Tr. 819:7-24 (Kaur).

Administration steps: Finally, the evidence at trial showed that the claimed administration steps of claim 1 of the '398 patent were well-known in the art, and Nexus presented no evidence to dispute this. Tr. 787:17-24 (Powell); DTX-236.2. Ephedrine sulfate products have been administered in syringes to treat hypotension for decades.

2. There is insufficient evidence to support a finding that the claimed stability characteristics were unexpected

Because all the evidence presented at trial demonstrates that the formulation, manufacturing, administration, and test condition limitations were obvious over the AKOVAZ concentrate product and Akers, and no reasonable jury could have found otherwise, Nexus is left with the stability limitations in its claims as the only avenue for non-obviousness. But these limitations cannot support the non-obviousness verdict either. The evidence at trial showed that it was well known in the art that ephedrine sulfate is highly stable, particularly when stored in glass containers like the prior art AKOVAZ concentrate product. *See* DTX-274.3 (Chou 1926) (explaining that salts of ephedrine were found to be "exceedingly stable" even when boiled); Tr.

at 865:14-866:10 (Myers); DTX-17.11 (Nexus referring to ephedrine sulfate as "very stable in aqueous solution"); DTX-267.5 (showing a two-year shelf life for AKOVAZ concentrate in glass vial). In light of that known stability, the evidence presented at trial overwhelmingly demonstrates that the claimed 5 mg/mL formulation would have been expected to meet the claimed stability limitations when stored in glass like AKOVAZ concentrate, which is permitted by the claims, and there is no substantial evidence to the contrary. *See In re Klein by Klein*, 987 F.2d 1569, 1570 (Fed. Cir. 1993) (where a claim covers multiple embodiments, a "§ 103 rejection is proper if the prior art demonstrates the obviousness of any one of them").

The specific stability limitations at issue in the asserted claims of the '369 and '398 patents are (1) an ephedrine sulfate concentration at least 95% of the packaged concentration, (2) a bacterial endotoxin level not more than 7 EU/mg, (3) a level of any one unknown individual impurity of not more than 0.2%, and (4) pH within 0.5 units of the initial pH. As demonstrated at trial, the prior art AKOVAZ concentrate product had ***each*** of these claimed stability characteristics after being stored in glass containers at the exact claimed glass storage conditions. And it maintained all the claimed characteristics not just for 6 or 12 months, as claimed, but for the full ***four years*** the product was tested for stability, as shown below:

Cod. 510391	Lot No. 00026A	*Akovaz inj 50 mg/ml*									
Validity of product:	24 months					Study No.:	N/A				
Date of production:	Jan 25, 2017					Ref. Stability protocol:	STPRT285 ver. 05				
Expiry date:	Jan 25, 2019					No. of vials required:	1350 (54 packs)				
Primary packaging:	Nuova Ompi clear type I vial, code 241156; Daiwyler V9024 grey chlorobutyl rubber stopper, code 272030; West aluminium seal with violet flip-off, code 272029					Beginning	Feb 17, 2017				
Secondary packaging:	N/A					End of stability:	Feb 17, 2021				
Batch size:	83,333 vials					Storage condition:	25°C 60% RH				
Note:	Commercial batches follow-up stability - *INVERTED POSITION*										

Test Parameters	Specifications	T0	1 month	3 months	6 months	9 months	12 months	18 months	Expiry date	36 months	48 months
Analytical procedure →		P6-0131 007 N1-0131/I1-0131	P6-0131 008	P6-0131 008	P6-0131 008	P6-0131 011	P6-0131 012 N1-0131/I1-0131	P6-0131 014/015	P6-0131 015 N1-0131/I1-0131	P6-0131 016 N1-0131/I1-0131	P6-0131 017 N1-0131/I1-0131
Appearance of the drug product	Clear, colorless solution	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform	Conform
Particulate Matter per container	≥ 10 µm NMT 6000 per container ≥ 25 µm NMT 600 per container	5 0	0 0	1 0	1 0	1 0	0 0	0 0	13 0	102 0	9 0
pH	6.8 – 6.7	5,8	5,8	5,8	5,8	5,7	5,5	5,5	5,2	5,3	5,3
Assay	95.0 – 105.0 % of the labelled amount	101,3%	101,4%	100,8%	101,0%	102,1%	104,1%	102,3%	101,7%	102,2%	102,2%
Related substances - Unknown impurities - Total	≤ 0.2% for any unidentified peak ≤ 1%	< LOQ (RRT 0.64) < LOQ	n.d. n.d.	n.d. n.d.	n.d. 0%	n.d. < LOQ	n.d. < LOQ	n.d. 0%	n.d. 0%	n.d. 0%	n.d. 0%
Pseudoephedrine (both enantiomers combined)	≤ 0.4%	< LOQ	n.d.	n.d.	0,1%	< LOQ	< LOQ	0,1%	0,1%	0,1%	0,1%
Chiral impurity	[ephedrine (+), (S,R)] ≤ 0.5%	< LOQ	< LOQ	< LOQ	< LOQ	< LOQ	n.d.	< LOQ	< LOQ	< LOQ	< LOQ
Sterility	Complies	Sterile	-	-	-	-	Sterile	-	Sterile	Sterile	Sterile
Endotoxin	≤ 1.7 EU/mg	<0,24 EU/mg	-	-	-	-	<0,24 EU/mg	-	<0,24 EU/mg	<0,24 EU/mg	<0,3 EU/mg
Note		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

DTX-325 (four-year stability data for AKOVAZ concentrate lot 26A).

The undisputed evidence at trial showed that the AKOVAZ concentrate product was publicly available before Nexus filed for its patents. For example, the evidence showed that lot 00026A, which was tested for stability and has the characteristics in the stability data shown above, was manufactured in January 2017 and ***commercially sold*** prior to May 16, 2019. DTX-320 (showing that lot 00026A was commercially sold); Tr. 897:13-898:4 (Myers). A product that was on sale to the public before the critical date becomes "a [prior art] reference under section 103 against the claimed invention." *See Pfaff v. Wells Elec. Inc.*, 124 F.3d 1429, 1436 (Fed. Cir. 1997); *Dippin' Dots, Inc. v. Mosey*, 476 F.3d 1337, 1344 (Fed. Cir. 2007) (finding that patentee's precritical date sales made the product sold prior art for purposes of determining the obviousness of the claimed invention).

This undisputedly prior art AKOVAZ concentrate product met all the claimed stability requirements and that product, with its properties, is prior art. *Cf. Pronova Biopharma Norge AS v. Teva Pharms. USA, Inc.*, 549 F. App'x 934, 943 (Fed. Cir. 2013) ("Where, as here, however, a compound is provided without restriction to one highly skilled in the art, that compound's formulation is disclosed in detail, and the formulation is subject to confirmatory testing, no other activity is needed to render that use an invalidating one."). As discussed below, Nexus simply claimed the characteristics of the prior art, the majority of which are required by industry standards. The only reasonable finding on this record is that the claims are obvious.

Ephedrine sulfate concentration, endotoxins, and impurities: As to the limitations requiring 95% of the packaged ephedrine sulfate concentration, a bacterial endotoxin level not more than 7 EU/mg, and an unknown individual impurity level of not more than 0.2%, these limits are all expressly required by the industry standards in the USP Monograph for ephedrine

sulfate. DTX-588.3-4; Tr. at 823:6-18, 827:2-829:19 (Kaur) ("It's an expectation that for a USP product, at minimum, those established acceptance criteria should be met.").

The jury's verdict that claim 7 of the '752 patent, which contains the 95% concentration limitation, is obvious demonstrates that the jury found at least one of these USP-based limitations to be obvious. *See Polara Eng'g*, 894 F.3d at 1351. In addition, as shown at trial, the AKOVAZ concentrate product is labeled as a USP product, so a POSA would have understood that the AKOVAZ concentrate must meet all the USP requirements, including the claimed concentration, endotoxin, and impurity requirements, for its entire two-year shelf life. DTX-236.1; Tr. at 874:7-18 (Myers); DTX-267.5 (showing a two-year shelf life for AKOVAZ concentrate). And, as shown above, the data for the AKOVAZ concentrate demonstrates that it met those requirements not only for two years, but out to four years. DTX-1.15653 at -687-688; DTX-325; Tr. at 901:14-902:3 (Myers). Nexus did not present any contrary evidence.

pH within 0.5 units: The final stability requirement in the claims is that the 5 mg/mL ephedrine sulfate formulation, stored at the claimed conditions for the required time, must maintain a pH level that is within 0.5 pH units of the starting pH. The USP Monograph for ephedrine sulfate requires that an ephedrine sulfate product stay within a pH range of 4.5-7.0, so a POSA would understand that the AKOVAZ concentrate stays in that range for at least two years. DTX-588.4; Tr. at 872:10-18 (Myers). To get patent claims, however, Nexus claimed a narrower range within the required pH range, even though the narrower range has no criticality or clinical benefit, as was undisputed at trial. Tr. at 798:19-25 (Powell); Tr. at 939:9-17 (Myers).

But even that gambit cannot support the non-obviousness verdict because, as discussed above, the prior art AKOVAZ concentrate product already teaches that the pH of ephedrine sulfate stored in glass containers simply does not vary more than 0.5 units. DTX-325. Nexus is

simply claiming what is already taught. Independently, because Nexus's 0.5 pH requirement is just a selection of a narrow pH range within the range of 4.5 to 7.0 disclosed as the specification on the prior art AKOVAZ concentrate label (DTX-236.6), it is obvious. *See In re Peterson*, 315 F.3d 1325, 1329-30 (Fed. Cir. 2003) ("Selecting a narrow range from within a somewhat broader range disclosed in a prior art reference is no less obvious than identifying a range that simply overlaps a disclosed range.").

The ***only*** difference between the prior art AKOVAZ concentrate and the claimed 5 mg/mL formulation is dilution with 9 mg/mL sodium chloride and water (i.e., normal saline). Tr. at 832:2-833:4 (Kaur), 841:16-22; DTX-62.1-2. And it is undisputed that this dilution is explicitly instructed by the AKOVAZ label. DTX-236. As the evidence at trial showed, in preparing this diluted 5 mg/mL product, according to the claimed well-known manufacturing steps as taught in Akers, a POSA would have expected the product to meet all the claimed stability requirements under the claimed conditions. Tr. 927:25-928:18 (Myers). Where, as here, the formulation, manufacturing steps, and testing steps are all well-known in the art, the resulting stability characteristics are obvious because they are simply "the natural result of the combination of elements explicitly disclosed by the prior art." *Hospira, Inc. v. Fresenius Kabi USA, LLC*, 946 F.3d 1322, 1329 (Fed. Cir. 2020).

What was Nexus's response at trial to this devastating evidence of obviousness? Knowing that the AKOVAZ concentrate stability data is fatal to its claims, Nexus did the unthinkable—it had its paid expert, Dr. Fix, rely on evidence Nexus itself believed to be ***false***. The ***only*** piece of evidence Nexus presented to suggest that a POSA thought it would vary beyond 0.5 pH units in a diluted ephedrine sulfate product is a self-interested statement in a patent to another company (Nevakar) working on diluted ephedrine sulfate products. Tr. at

1025:6-1027:9, 1076:1-1077:9 (Fix). According to the Nevakar patent, "[d]iluted solutions of ephedrine sulfate are known to have pH drifts of up to 2 pH units." PTX-9 at 5:53-59. But in a different lawsuit related to that patent (that its expert was not even aware of), Nexus itself said that the statement about supposed pH drift is ***false***. DTX-1090.0004, .0029; Tr. at 1069:19-21 (Fix). Specifically, according to Nexus, the statement about pH drift is a "misrepresentation" and "the data cited in support did not actually show the pH drift claim that was being made." DTX-1090.0029. Nexus's argument, made in a court filing on Nexus's behalf by the very same attorneys now arguing that this Nevakar patent statement supports an expectation of pH drift here, destroys any evidentiary value for the Nevakar patent.

The evidence thus plainly shows that the AKOVAZ concentrate combined with Akers teaches all the limitations of the asserted claims of the '398 and '369 patents. As for reasonable expectation of success, the evidence overwhelmingly demonstrates that POSAs were well aware of the stability of ephedrine sulfate products and would have reasonably expected that preparing a 5 mg/mL formulation by well-known sterile processing steps, using the same glass containers in which the AKOVAZ concentrate product was stable for four years, would result in a product that meets the claimed stability limitations. A reasonable expectation of success does not require "absolute predictability" or "conclusive proof" that something would achieve the recited results. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988); *In re Copaxone Consol. Cases*, 906 F.3d 1013, 1026 (Fed. Cir. 2018). Instead, all that is required is a ***reasonable*** expectation of success, which the jury already found as to claim 7 of the '752 patent. *In re Copaxone*, 906 F.3d at 1026; *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). In light of all the evidence presented, a finding of lack of expectation of success is unsupported by substantial evidence.

3. There are no secondary considerations supporting non-obviousness

Nexus cannot rely on secondary considerations to support a finding of non-obviousness.

In determining that claim 7 of the '752 patent is invalid as obvious, the jury plainly found that Nexus's arguments for secondary considerations were not compelling. And that finding is supported by the evidence. As to long-felt need in particular, Dr. Powell, the only expert who has actually used and administered ephedrine sulfate products to patients, testified that the prior art AKOVAZ concentrate and compounded syringe products are acceptable, that they continue to be safely used, and that there was no need in the art for the product recited in Nexus's claims. Tr. at 777:20-25, 788:18-789:4, 796:12-797:9 (Powell) (explaining that "[h]ospitals all around this country today use compounded syringes safely and effectively"). Nexus's "evidence"—from a pharmacist who does not and, indeed, cannot, administer ephedrine sulfate to patients—was that no one would ever buy the compounded products if an FDA-approved product is available. Tr. at 4541-13, 467:23-468:8 (Emamifar). But that testimony is untrue—it is directly refuted by the fact that hospitals ***are still*** buying and using both AKOVAZ concentrate and the compounded syringes, even though both Nexus's and Exela's products are on the market.

Based on the evidence, no reasonable juror could have found that the asserted claims of the '369 and '398 patents were not obvious over the AKOVAZ concentrate product and Akers.

VI. CONCLUSION

For all these reasons, Exela respectfully requests that the Court enter judgment as a matter of law that Exela does not infringe claim 7 of the '752 patent, that Exela does not willfully infringe claim 7 of the '752 patent, and that claims 6 and 9 of the '369 patent and claim 1 of the '398 patent are invalid as obvious over the prior art.

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